(FILE 'HOME' ENTERED AT 12:12:04 ON 07 NOV 2006)

FILE 'REGISTRY' ENTERED AT 12:12:16 ON 07 NOV 2006
L1 1 S DONEPEZIL/CN

FILE 'CAPLUS' ENTERED AT 12:12:30 ON 07 NOV 2006
L2 427 S L1 AND ALZHEIM?
L3 51 S L2 AND MMSE
L4 8 S L3 AND SEVERE

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=> s donepezil/cn
L1            1 DONEPEZIL/CN

=> file caplus
COST IN U.S. DOLLARS                                    SINCE FILE      TOTAL
                                                           ENTRY    SESSION
FULL ESTIMATED COST                                         5.20       5.41

FILE 'CAPLUS' ENTERED AT 12:12:30 ON 07 NOV 2006
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=> s l1 and alzheim?
          666 L1
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        41977 ALZHEIM?
L2        427 L1 AND ALZHEIM?

=> s l2 and MMSE
          419 MMSE
L3         51 L2 AND MMSE

=> s l3 and severe
       156987 SEVERE
L4          8 L3 AND SEVERE

=> d l4 1-8 ti

L4   ANSWER 1 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Response to rivastigmine or donepezil in Alzheimer's patients
     with symptoms suggestive of concomitant Lewy body pathology. [Erratum to
     document cited in CA145:117166]

L4   ANSWER 2 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Effect of age on response to rivastigmine or donepezil in patients with
     Alzheimer's disease

L4   ANSWER 3 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Response to rivastigmine or donepezil in Alzheimer's patients
     with symptoms suggestive of concomitant Lewy body pathology

L4   ANSWER 4 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor
     in patients with Alzheimer's disease

L4   ANSWER 5 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   An Observational Clinical Study of the Efficacy and Tolerability of
     Donepezil in the Treatment of Alzheimer's Disease

L4   ANSWER 6 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Donepezil and rivastigmine in the treatment of Alzheimer's
     disease: a best-evidence synthesis of the published data on their efficacy
     and cost-effectiveness

L4   ANSWER 7 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Cognitive deficits in Alzheimer's disease: treatment with
     acetylcholinesterase inhibitor agents

L4   ANSWER 8 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Efficacy of acetylcholinesterase inhibitors versus nootropics in
     Alzheimer's disease: A retrospective, longitudinal study


=> d l4 1-8 ti abs bib

L4   ANSWER 1 OF 8  CAPLUS  COPYRIGHT 2006 ACS on STN
TI   Response to rivastigmine or donepezil in Alzheimer's patients
     with symptoms suggestive of concomitant Lewy body pathology. [Erratum to
     document cited in CA145:117166]
AB   On page 56, left column, line 5, "192" is incorrect and should read "92".
AN   2006:1091365  CAPLUS
TI   Response to rivastigmine or donepezil in Alzheimer's patients
     with symptoms suggestive of concomitant Lewy body pathology. [Erratum to
     document cited in CA145:117166]
AU   Touchon, Jacques; Bergman, Howard; Bullock, Roger; Rapatz, Gunter; Nagel,
     Jennifer; Lane, Roger
CS   INSERM 361 CHU, Montpellier, Fr.
SO   Current Medical Research and Opinion (2006), 22(8), 1451
     CODEN: CMROCX; ISSN: 0300-7995
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PB LibraPharm Ltd.
DT Journal; Errata
LA English

L4 ANSWER 2 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Effect of age on response to rivastigmine or donepezil in patients with Alzheimer's disease
AB Background: Younger Alzheimer's disease (AD) patients appear to differ genetically and neuropathol. from older AD patients, and may experience a more aggressive disease course compared with older patients. A randomized trial investigated the efficacy and tolerability of rivastigmine, an inhibitor of acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE), and donepezil, an AChE-selective inhibitor, in patients with AD over a 2-yr period. This retrospective anal. investigated whether younger and older patients showed differential tolerability and efficacy responses to cholinesterase inhibitor treatment. Methods: For the current anal., patients were divided according to age at baseline: those aged < 75 years and those aged ≥ 75 years. Efficacy measures were the Severe Impairment Battery (SIB), Neuropsychiatric Inventory (NPI), Global Deterioration Scale (GDS), Mini-Mental State Examination (MMSE) and the AD Cooperative Study Activities of Daily Living scale (ADCS-ADL). Changes in efficacy parameters and adverse event frequencies were calculated for rivastigmine and donepezil-treated patients in both age groups. Exploratory analyses were also conducted on SIB, ADCS-ADL and NPI in patients who consented to pharmacogenetic testing at baseline. Genotyping of the apolipoprotein E (APOE) ε4 allele and the BuChE K-variant was conducted using the TaqMan assay. Main efficacy analyses were based on an intent-to-treat last observation carried forward (ITT-LOCF) population. Results: Of the 994 patients who received the study drug, 362 (36.4%) were younger than 75 years and 632 (63.6%) were aged 75 years or over. Rivastigmine provided significant benefits in younger patients compared with donepezil on the NPI-10, NPI-12, NPI-D, GDS and ADCS-ADL (all $p < 0.05$, ITT-LOCF). With the exception of the NPI-D in favor of donepezil ($p < 0.05$, ITT-LOCF), no significant treatment differences were observed in older patients. Younger patients with two wild-type BuChE alleles had a significantly greater response to rivastigmine than donepezil on the ADCS-ADL ($p < 0.01$, ITT-LOCF) and SIB ($p < 0.05$, ITT-LOCF). The most common adverse events were nausea and vomiting and these were more frequent in rivastigmine-treated patients. Conclusion: In this sub group anal., patients younger than 75 years of age showed greater treatment responses to rivastigmine than donepezil. Anal. of response by BuChE genotype suggests that this differential effect may be due to the inhibition of BuChE, in addition to AChE, by rivastigmine.
AN 2006:389254 CAPLUS
DN 145:306490
TI Effect of age on response to rivastigmine or donepezil in patients with Alzheimer's disease
AU Bullock, Roger; Bergman, Howard; Touchon, Jacques; Gambina, Giuseppe; He, Yunsheng; Nagel, Jennifer; Lane, Roger
CS Kingshill Research Centre, Swindon, UK
SO Current Medical Research and Opinion (2006), 22(3), 483-494
CODEN: CMROCX; ISSN: 0300-7995
PB LibraPharm Ltd.
DT Journal
LA English
RE.CNT 33 THERE ARE 33 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 3 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Response to rivastigmine or donepezil in Alzheimer's patients with symptoms suggestive of concomitant Lewy body pathology
AB Background: A double-blind randomized trial evaluated the efficacy and tolerability of rivastigmine and donepezil in patients with

Alzheimer's disease (AD) over 2 years. Baseline data indicated that some patients had symptoms suggestive of concomitant Lewy body disease. This retrospective anal. investigated whether AD patients with and without symptoms suggesting concomitant Lewy body pathol. demonstrated different responses to therapy. Methods: AD patients were divided by the presence/absence of symptoms suggestive of concomitant Lewy body disease. These were identified by a concomitant diagnosis of dementia with Lewy bodies and/or use of anti-parkinsonian medication at baseline. Baseline characteristics, demographics, changes on efficacy parameters and adverse event (AE) frequencies were calculated for rivastigmine- and donepezil-treated patients. Efficacy parameters were the Severe Impairment Battery (SIB), Mini-Mental State Examination (MMSE), Global Deterioration Scale (GDS), Neuropsychiatric Inventory (NPI) and AD Cooperative Study Activities of Daily Living scale (ADCS-ADL). Main efficacy analyses were based on an intent-to-treat last observation carried forward (ITT-LOCF) population. Results: Both populations reached mean doses of rivastigmine and donepezil that were within therapeutic ranges. Nine hundred and ninety-four AD patients received study drug, of whom 49 (4.9%) had symptoms suggestive of concomitant Lewy body disease (25 rivastigmine, 24 donepezil). In this subpopulation, changes from baseline after 2 years of treatment with rivastigmine were significantly better than those seen with donepezil on the SIB, MMSE and ADCS-ADL (ANCOVA or Wilcoxon analyses, $p < 0.05$, IIT-LOCF). Statistical significance was not maintained in non-ITT-LOCF analyses, except for EP analyses on the SIB and ADCS-ADL (both $p < 0.05$). Rivastigmine also provided significantly better functioning than donepezil in patients without Lewy body pathol., as shown by a significant treatment difference at endpoint on the ADCS-ADL ($p < 0.05$, ITT-LOCF; not maintained in non-ITT-LOCF analyses). NPI changes from baseline did not differ significantly between treatment groups. AD patients with symptoms suggestive of concomitant Lewy body disease receiving rivastigmine or donepezil experienced fewer gastrointestinal side effects, leading to fewer discontinuations due to AEs, compared with patients without Lewy body pathol. Conclusion: In this retrospective anal., AD patients who had symptoms suggestive of concomitant Lewy body disease appeared to show greater treatment responses to rivastigmine than to donepezil, and experienced fewer adverse events under either drug, compared with patients without Lewy body pathol.

AN 2006:155973 CAPLUS
DN 145:117166
TI Response to rivastigmine or donepezil in Alzheimer's patients with symptoms suggestive of concomitant Lewy body pathology
AU Touchon, Jacques; Bergman, Howard; Bullock, Roger; Rapatz, Gunter; Nagel, Jennifer; Lane, Roger
CS INSERM 361, CHU, Montpellier, Fr.
SO Current Medical Research and Opinion (2006), 22(1), 49-59
CODEN: CMROCX; ISSN: 0300-7995
PB LibraPharm Ltd.
DT Journal
LA English
RE.CNT 51 THERE ARE 51 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 4 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor in patients with Alzheimer's disease
AB Cholinesterase (ChE) inhibitors are the only medications approved for the treatment of Alzheimer's disease (AD). The features of ChE inhibitors differ considerably. In addition to acetylcholinesterase (AChE) inhibition, rivastigmine also inhibits butyrylcholinesterase (BuChE), providing dual AChE and BuChE inhibition. An observational study was performed to determine the response in routine clin. practice to switching AD patients to rivastigmine from a selective AChE inhibitor when that treatment no longer delivered a satisfactory clin. response. A

prospective, multicenter, 3-mo observational trial in patients with mild to moderately severe AD (adjusted Mini Mental State Examination [MMSE] score 10-26) deteriorating (at least 2 adjusted MMSE points in last 6 mo) on selective AChE inhibitor treatment. Adjusted MMSE, activities of daily living (ADL) and instrumental activities of daily living (IADL), the Zarit caregiver burden and global function (short Clin. Global Impression of Change, CGIC) scores were noted before the switch and 3 mo after the switch. Two hundred twenty-five patients entered the study. The switches made were from donepezil to rivastigmine (D-R) in 188 patients, galantamine to rivastigmine (G-R) in 33 patients and donepezil to galantamine (D-G) in four patients. Ten patients discontinued due to adverse events and eight for other reasons. More than half of the switches were within 36 h of a patient's first treatment visit. In the D-R and G-R groups, 67.7% and 66.7% of patients responded (CGIC score ≤ 4), resp. In non-responders, worsening (CGIC score 5-7) was mild in approx. 80% or more of patients. Adjusted MMSE improved after the switch from both donepezil and galantamine to rivastigmine (+0.69 ± 3.2, p = 0.008 and +0.6 ± 1.6, p = 0.05, resp.). Mean ADL, IADL and Zarit scores remained stable. The proportion of patients on concomitant antipsychotic therapy diminished by 30.5% and benzodiazepines were discontinued in all patients, except one. AD patients deteriorating on selective AChE inhibitor treatment can benefit from switching to a dual AChE-BuChE inhibitor, such as rivastigmine, in terms of stabilization of disease, improvement in cognitive function and reduction in the burden of concomitant psychoactive treatment. The switch was well tolerated. Confirmation of these results is required in a controlled study.

AN 2006:779 CAPLUS
DN 144:343421
TI Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor in patients with Alzheimer's disease
AU Bartorelli, L.; Giraldi, C.; Saccardo, M.; Cammarata, S.; Bottini, G.; Fasanaro, A. M.; Trequattrini, A.
CS The Upgrade Study Group, Geriatrics Unit, S. Eugenio Hospital, Rome, Italy
SO Current Medical Research and Opinion (2005), 21(11), 1809-1817
CODEN: CMROCX; ISSN: 0300-7995
PB LibraPharm Ltd.
DT Journal
LA English
RE.CNT 31 THERE ARE 31 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 5 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI An Observational Clinical Study of the Efficacy and Tolerability of Donepezil in the Treatment of Alzheimer's Disease
AB An open-label, observational Post-Marketing Surveillance (PMS) study was undertaken in Germany to examine the efficacy and tolerability of donepezil in routine clin. practice. Alzheimer's disease (AD) patients were treated with donepezil (5 or 10 mg once daily) and observed for a period of approx. 3 mo. Study assessments included the Mini-Mental State Examination (MMSE), the Nurses' Observation Scale for Geriatric Patients (NOSGER), and adverse events (AEs). A total of 2,092 patients (mean age 73.0 yr; mean ± SD MMSE score 17.8±5.8) were included in the efficacy assessments. MMSE and NOSGER scores showed statistically significant improvements in the total patient population and in the subpopulations with severe AD or AD with concomitant Parkinsonian symptoms (ADPS cohort). AEs were reported in a total of 12% of patients and were mostly due to peripheral cholinergic effects. In this observational PMS study, donepezil was shown to be an effective and well-tolerated therapy in the overall patient population, in patients with severe AD, and in the ADPS cohort.
AN 2003:200023 CAPLUS
DN 139:301794
TI An Observational Clinical Study of the Efficacy and Tolerability of

Donepezil in the Treatment of Alzheimer's Disease
AU Hager, Klaus; Calabrese, Pasquale; Froelich, Lutz; Goebel, Claus; Berger, Frank M.
CS Department of Geriatrics, Henrietten Hospital, Hannover, Germany
SO Dementia and Geriatric Cognitive Disorders (2003), 15(4), 189-198
CODEN: DGCDFX; ISSN: 1420-8008
PB S. Karger AG
DT Journal
LA English
RE.CNT 40 THERE ARE 40 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 6 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Donepezil and rivastigmine in the treatment of Alzheimer's disease: a best-evidence synthesis of the published data on their efficacy and cost-effectiveness
AB A review. Various drugs have been approved for the treatment of Alzheimer's disease (AD) in the United States and Canada, including donepezil and rivastigmine, although questions remain as to their efficacy, effectiveness, and long-term benefits. The goal of this study was to conduct a best-evidence synthesis of data on the efficacy and cost-effectiveness of donepezil and rivastigmine in the treatment of AD. Relevant published randomized controlled trials (RCTs) and Phase IV open-label extension studies (excluding abstrs.) were identified through searches of MEDLINE, HealthSTAR, and PsycINFO for the period Jan. 1984 to Oct. 2001. The bibliogs. of retrieved articles were searched for addnl. publications. For inclusion in the best-evidence synthesis, clin. trials had to pass a blinded quality assessment (score ≥5 on the Jadad scale) and use National Institute of Neurol. and Communicative Disease and Stroke-Alzheimer's Disease and Related Disorders Association diagnostic criteria. Economic studies were selected using National Health Service Center for Reviews and Dissemination criteria for reporting critical summaries of economic evaluations. Nine RCTs of donepezil and 2 of rivastigmine were identified and met inclusion criteria for the best-evidence synthesis. Eight donepezil trials and both rivastigmine trials included patients with mild AD (Mini-Mental State Examination [MMSE] score, 15-27) or moderate AD (MMSE score, 8-14); 1 donepezil trial included patients with moderate or severe AD (MMSE score, 0-7). In the RCTs of donepezil, the mean decrease in scores on the Alzheimer's Disease Assessment Scale-cognitive sub-scale (ADAS-cog) was greater with active treatment than with placebo (lower scores indicate less cognitive deterioration). In the RCTs of rivastigmine, ADAS-cog scores decreased over the follow-up period with both active treatment and placebo; however, scores decreased more with active treatment. Three Phase IV studies of donepezil and 1 Phase IV study of rivastigmine were identified. Their results were consistent with those of the RCTs. Ten economic studies (7 donepezil, 3 rivastigmine) were identified and reviewed. In 4 of the donepezil studies and all 3 rivastigmine studies, use of the drug cost less than a no-drug strategy. The efficacy data indicate that both donepezil and rivastigmine can delay cognitive impairment and deterioration in global health for at least 6 mo in patients with mild to moderate AD. Patients receiving active treatment will have more favorable ADAS-cog scores for at least 6 mo, after which their scores will begin to converge with those of patients receiving placebo. Differences in methodol., types of direct or indirect costs included, and sources of cost data made it difficult to compare and synthesize findings of the economic studies; therefore, the cost-effectiveness data are inconclusive.
AN 2002:591114 CAPLUS
DN 137:149694
TI Donepezil and rivastigmine in the treatment of Alzheimer's disease: a best-evidence synthesis of the published data on their efficacy and cost-effectiveness
AU Wolfson, Christina; Oremus, Mark; Shukla, Vijay; Momoli, Franco; Demers,

Louise; Perrault, Anne; Moride, Yola
CS Centre for Clinical Epidemiology and Community Studies, S.M.B.D. Jewish General Hospital, Can.
SO Clinical Therapeutics (2002), 24(6), 862-886
CODEN: CLTHDG; ISSN: 0149-2918
PB Excerpta Medica, Inc.
DT Journal; General Review
LA English
RE.CNT 54 THERE ARE 54 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 7 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Cognitive deficits in Alzheimer's disease: treatment with acetylcholinesterase inhibitor agents
AB The use of acetylcholinesterase (AChe) inhibitors seems to be a promising therapeutic strategy against cognitive impairment of Alzheimer's disease (AD). We evaluated the safety and the efficacy of two AChe inhibitor agents, donepezil and rivastigmine, in the treatment of mild to moderately severe AD. Twenty-seven patients were recruited for the study. They met DSM-IV criteria for uncomplicated AD and NINCDS-ADRDA criteria for probable or possible AD of mild to moderate severity. Mini mental state examination (MMSE) scores of 10-21 at screening were required. Patients' age was between 53-77 yr. Sixteen patients were treated with donepezil, 5 mg/day, and 11 subjects received rivastigmine, 6-9 mg/day for 30 wk. The rating instruments used were the MMSE , the cognitive subscale of the AD assessment scale (ADAS-Cog), and the phys. self-maintenance scale (PSMS). The assessment was carried out at baseline and at weeks 6, 12, 18, 24, and 30. The results demonstrated the pos. effects of these agents on the cognitive and functional pictures in patients with mild to moderately severe AD. The adverse events related to treatment were generally not troublesome, and were of short duration (nausea, vomiting, dizziness, and diarrhea).
AN 2001:633476 CAPLUS
DN 135:352692
TI Cognitive deficits in Alzheimer's disease: treatment with acetylcholinesterase inhibitor agents
AU Fuschillo, C.; La Pia, S.; Campana, F.; Pinto, A.; De Simone, L.
CS Department of Mental Health, Neuropsychogeriatric Ward of Pollena Trocchia, Pollena Trocchia (Napoli), I-80040, Italy
SO Archives of Gerontology and Geriatrics, Supplement (2001), 7(Cognitive, Affective and Behavior Disorders in the Elderly), 151-158
CODEN: AGGSEU; ISSN: 0924-7947
PB Elsevier Science Ireland Ltd.
DT Journal
LA English
RE.CNT 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD
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L4 ANSWER 8 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN
TI Efficacy of acetylcholinesterase inhibitors versus nootropics in Alzheimer's disease: A retrospective, longitudinal study
AB The aim of this study was to investigate the efficacy of nootropics (piracetam, aniracetam, nimodipine and dihydroergocristine) vs. acetylcholinesterase inhibitors (AChE-Is) (tacrine and donepezil) in the treatment of Alzheimer's disease. This is a retrospective study of 510 patients with Alzheimer's disease. To determine clin. efficacy of treatment, we used the mean change over time in scores for the following tests: the Mini-Mental State Examination (MMSE); the Cambridge Cognitive Examination for the Elderly; and the Functional Rating Scale for Symptoms of Dementia. In all patients and in patients with severe Alzheimer's disease (baseline MMSE <
11), no significant differences were seen in the neuropsychol. test scores between the two treatment groups. In patients with moderate dementia (baseline MMSE between 11 and 20), however, there was a

significantly greater deterioration, as shown on the CAMCOG scale, after 12 mo' treatment for patients receiving AChE-Is compared with those receiving nootropics (-4.38 for AChE-Is group vs. 1.48 for nootropics group). For patients with mild dementia (baseline MMSE score between 21 and 26), there was a significantly greater deterioration on the MMSE scale for each time-point in the nootropics group compared with the AChE-Is group. In conclusion, we did not find any strong evidence that a difference in efficacy exists between AChE-Is and nootropics in the treatment of Alzheimer's disease.

AN 2001:246165 CAPLUS
DN 135:190250
TI Efficacy of acetylcholinesterase inhibitors versus nootropics in Alzheimer's disease: A retrospective, longitudinal study
AU Tsolaki, M.; Pantazi, T.; Kazis, A.
CS Third Department of Neurology, Aristotle University of Thessaloniki, Thessaloniki, Greece
SO Journal of International Medical Research (2001), 29(1), 28-36
CODEN: JIMRBV; ISSN: 0300-0605
PB Cambridge Medical Publications Ltd.
DT Journal
LA English
RE.CNT 30 THERE ARE 30 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT